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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,678	02/27/2002	Olivier Schwartz	03495-0217-00000	9442

7590 05/05/2004

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EXAMINER	
PARKIN, JEFFREY S	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/083,678	SCHWARTZ ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,8-12,15-17 and 19-23* is/are pending in the application.

4a) Of the above claim(s) *2,8-11,15,17 and 19-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,12 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04032002, 07292003,* 12032003
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Office Action

Status of the Claims

Applicants' election with traverse of Group I (claims 1, 12, and 16) in the communication dated 29 January, 2004, is acknowledged. The traversal is based upon the argument that it would not be a serious burden to examine the groups together. Establishment of *prima facie* evidence for a serious burden requires the demonstration, by appropriate explanation, of either separate classification, separate status in the art, or a different field of search as defined in M.P.E.P. § 808.02. The following items adduce a *prima facie* showing of burden: 1) The inventions of Groups I-IX display both separate classifications and a separate status in the art as set forth in the last Office action. 2) The inventions of Groups I-IX are directed towards independent and distinct subject matter as clearly set forth in pages 2 and 3 of the restriction requirement. Accordingly, each invention will generate unique issues regarding novelty, patentability, and enablement. 3) Since the inventions disclosed *supra* are directed towards patentably distinct material, a search for one invention would not necessarily result in the identification of art that is concomitant with that required to address the issues generated by the other inventions. Applicants' arguments have been thoroughly considered but are not deemed persuasive for the reasons set forth *supra* and in the original restriction requirement. **The requirement is still deemed to be proper and is therefore made FINAL.**

Applicants amended claims 3 and 4 to read on claim 1 and would now be considered part of Group I. Accordingly, claims 1, 3, 4, 12, and 16 are currently under examination. Claim 20 appears to be directed toward a polypeptide immunogen comprising a CTL epitope and would constitute an independent and distinct invention in of

itself. Claims 2, 8-11, 15, 17, 19, and 20-23 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b).

37 C.F.R. §§ 1.821-1.825

This application clearly fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825. Applicants' attention is directed to the final rulemaking notice published at 55 F.R. 18230 (01 May, 1990) and 1114 O.G. 29 (15 May, 1990). Since the effective filing date is on or after 08 September, 2000, see the final rulemaking notice published in the Federal Register at 65 F.R. 54604 (08 September, 2000) and 1238 O.G. 145 (19 September, 2000). **Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper copy or compact disk copy of the "Sequence Listing", as well as, an amendment directing its entry into the application. Applicant must also provide a statement that the content of the sequence listing information recorded in the computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter as required by 37 C.F.R. §§ 1.821(e), 1.821(f), 1.821(g), 1.825(b), and 1.825(d).** If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the United States Patent and Trademark Office, such request in accordance with 37 C.F.R. § 1.821(e) may be submitted in lieu of a new CRF.

Applicant is reminded that nucleotide and/or amino acid sequences appearing in the specification (i.e., see pages 30 and 46) (including tables) and/or figures must be identified by the appropriate sequence identifier in accordance with 37 C.F.R. § 1.821(d). Sequence identifiers for sequences appearing in the drawings may appear in the Brief Description of the Drawings. Applicant must provide appropriate amendments to the specification

and/or drawings inserting the required sequence identifiers. If the amendments are extensive in nature, then a substitute specification should be provided.

Information Disclosure Statement

The information disclosure statements filed 03 April, 2002, 29 July, 2003, and 03 December, 2003, have been placed in the application file and the information referred to therein has been considered.

Claim Objections

Claims 1, 3, 4, 12, and 16 are objected to because of the following informalities: Applicants are reminded of the restriction requirement set forth in the last Office action. Applicants elected Group I which is directed toward an immunogenic composition comprising a first and second plasmid, both of which encode viral proteins. Compositions comprising RVVPs were not elected. The claims should be amended to reflect the restriction requirement.

35 U.S.C. § 112, Second Paragraph

Claims 1, 3, 4, 12, and 16 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

Claim 1 is particularly confusing since the precise characteristics of the "immunogenic composition" are not readily manifest. First, the composition is directed simply toward a composition comprising plasmid DNAs, which in of itself, would not necessarily be expected to be immunogenic. The compounds encoded

by the plasmids are immunogenic. Therefore, it is suggested the claims be amended to recite an "immunizing" composition or a composition capable of inducing a CTL-specific response. Second, the reference to selecting plasmids for their fusogenic properties is also confusing. The plasmids themselves would not be expected to be particularly fusogenic, however, the immunogens encoded by these proteins might be. The claims as presently drafted are clearly vague and indefinite and fail to clearly set forth the metes and bounds of the patent protection desired. The reference to an exogenous MHC-I pathway is also confusing. Since the plasmids are encoding antigens that will be expressed internally within the cell, the skilled artisan would reasonably expect these antigens to be processed utilizing internal processing pathways, not exogenous pathways. Appropriate correction is required.

The disclosure illustrates that HIV-1 epitopes derived from incoming virions are presented through an exogenous MHC-I pathway in dendritic cells and that this process is facilitated by virus-receptor interactions and fusion of the viral and cellular membranes. Therefore, it appears that the claimed invention should be directed toward compositions comprising plasmid DNAs that incorporate these various characteristics and functions. Applicants also need to clearly define the purpose of the composition. For instance, are the nucleic acids to utilized simply as expression vectors to prepare retroviral vector particles that are to be employed as immunogens, or are the plasmids themselves suppose to induce an endogenous MHC-I-response?

Claim 12 is also vague and indefinite since it references an exogenous antigen presentation pathway involving the administration of expression vectors that would presumably result in an endogenous presentation step. Moreover, the reference to "optionally testing" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention or not, and the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See M.P.E.P.

§ 2173.05(d). Appropriate correction is required.

Claim 16 also suffers from the same defects as the aforementioned claims. Applicants are invited to contact the Examiner for suggestions regarding the claim language.

Correspondence

The Art Unit location of your application in the Patent and Trademark Office has changed. To facilitate the correlation of related papers and documents for this application, all future correspondence should be directed to **art unit 1648**.

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 9:30 AM to 7:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (571) 272-0910 or (571) 272-0902, respectively. Direct general inquiries to the Technology Center 1600 receptionist at (571) 272-1600.

Formal communications may be submitted through the official facsimile number which is (703) 872-9306. Hand-carried formal communications should be directed toward the customer window located in Crystal Plaza Two, 2011 South Clark Place, Arlington, VA. Applicants are directed toward the O.G. Notice for further guidance. 1280 O.G. 681. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

01 May, 2004